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| 10/582,292 | 05/31/2007 | Chawnshang Chang | 24376.18.8402 | 1600 |

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| EXAMINER |
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HARRIS, ALANA M

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| ART UNIT | PAPER NUMBER |
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1643

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06/10/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. 10/582,292 | Applicant(s) CHANG, CHAWNSHANG | |
| | Examiner Alana M. Harris, Ph.D. | Art Unit 1643 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment and Arguments

1. Claims 1-52 are pending.

Claims 6-52, drawn to non-elected inventions is withdrawn from examination.

Claim 1 has been amended.

Claims 1-5 are examined on the merits to the extent an antibody is used to detect the androgen receptor.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Grounds of Objections

Claim Objections

3. Claim 1 is objected to because of the following informality: the conjunction, "and" should be deleted from line 2 and placed on line 4 between the recitations, "cancer," and "c) identifying". Correction is required.

New and Maintained Grounds of Rejection

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. ***THIS IS A NEW MATTER REJECTION.***

Applicant has amended claim 1 to include the underlined recitation,

“A method of screening a subject for breast cancer comprising: a) obtaining a tissue sample, and b) assaying for the presence of androgen receptor, wherein the presence of androgen receptor indicates an increased risk of or presence of breast cancer, c) identifying the subject as having an increased risk of breast cancer when the presence of androgen receptor is identified.”

Applicant has not pointedly expressed where in the specification support can be found for the claimed method with this newly added step. The Examiner does not note where in the disclosure this method of screening includes these three recited steps. Applicant should delete the new matter or explicitly note by page and line number where support is for the claimed method including this newly added step.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. The rejection of claims 1-5 under 35 U.S.C. 102(e) as being anticipated by Thompson/ U.S. Patent number 7,029,859 B2 (filed March 5, 2001) is maintained.

Applicant sets forth the criteria for establishing a proper rejection under 102(e) and the corresponding sections of the MPEP, see Remarks submitted March 3, 2010, page 7. Applicant asserts Thompson teaches treatment of metastatic cancers through suppressing expression of the caveolin gene, see Remarks submitted March 3, 2010, page 7, last paragraph. Applicant further notes Example 2 does not mention breast cancer and relates to castration-induced regression of mouse prostate cancer, see Remarks, page 8. Applicant's

Art Unit: 1643

arguments and points of view have been carefully considered, but found unpersuasive.

Applicant is reminded that their claims comprise two active steps, obtaining a tissue sample and assaying for the presence of the androgen receptor. Thompson discloses assessing androgen (AR) levels using a monoclonal antibody in tissues from both rodent and human model systems, see columns 22 and 23; and Figure 2. The tissue sample is not identified in the claims, hence can be from any source and the newly added step c) is a characterization of meeting the two active steps. Claim 1, step c) merely states the results of the two limitations or steps in the claim and adds nothing to the patentability or substance of the claim, hence it not given weight. It simply expresses the intended result of the positively recited process steps. Thompson's disclosure of caveolin does not preclude the instant rejection. Consequently, Thompson anticipates the claim and the rejection is maintained.

8. The rejection of claims 1, 2, 4 and 5 under 35 U.S.C. 102(b) as being anticipated by Fujimoto et al. (Laboratory Investigation 80(9): 1465-1471, September 2000) is maintained.

Applicant sets forth the criteria for establishing a proper rejection under 102(b) and the corresponding section of the MPEP, see Remarks submitted March 3, 2010, page 9. Applicant asserts Fujimoto discloses Extramammary Paget's Disease (EMPD), which is not breast cancer. While Applicant submits

Art Unit: 1643

Fujimoto does disclose “[a] tissue sample is obtained and androgen receptor is assayed...”, Fujimoto does not disclose the correlation between the androgen receptor and breast cancer, see Remarks, page 10. Applicant's arguments and points of view have been carefully considered, but found unpersuasive.

As stated previously in the 102(e) rejection the claimed invention reads on comprising two active steps, obtaining a tissue sample and assaying for the presence of the androgen receptor. Applicant has submitted that Fujimoto reads on both limitations, see page 10 of the Remarks, 1st sentence; and Fujimoto, page 1469, Materials and Methods section. The correlation set forth in Applicant's claim 1 is still established in Fujimoto based on it reading on the two limitations or steps in the claim. Consequently, Fujimoto anticipates the claim and the rejection is maintained.

9. The rejection of claims 1, 2 and 4 under 35 U.S.C. 102(a) as being anticipated by Moinfar et al. (Cancer 98(4): 703-711, August 15, 2003) is maintained.

Applicant sets forth the criteria for establishing a proper rejection under 102(a) and the corresponding section of the MPEP, see Remarks submitted March 3, 2010, page 10. Applicant submits Moinfar does disclose investigation of the expression of androgen receptor in breast carcinomas, however “Moinfar... [does] *not* describe a correlation between androgen receptor and the increased risk or presence of breast cancer”., see Remarks, page 10.

Art Unit: 1643

Applicant's arguments and points of view have been carefully considered, but found unpersuasive.

As set forth by Applicant in their Remarks and of record in the first action on the merits (FAOM) mailed September 3, 2009, Moinfar discloses immunohistochemical assays for AR in samples of breast carcinomas with antibodies, see page 704, Materials and Methods section. Moinfar's disclosure is regarded by the Examiner as meeting the limitations of the claims. The correlation set forth in Applicant's claim 1, step c) is established Moinfar because the document reads on the two limitations or steps in the claim as a) and b). Consequently, Moinfar anticipates the claim and the rejection is maintained.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The rejection of claims 1-5 under 35 U.S.C. 103(a) as being unpatentable over Fujimoto et al. (Laboratory Investigation 80(9): 1465-1471, September 2000), and further in view of Thompson/ U.S. Patent number 7,029,859 B2 (filed March 5, 2001) is maintained.

Applicant sets forth the criteria for establishing a proper rejection under 103(a) and making a *prima facie* case of obviousness, see Remarks submitted March 3, 2010, pages 13-15. Applicant's arguments are based on the primary reference, Fujimoto does not teach the claimed invention. Applicant's arguments and points of view have been carefully considered, but found unpersuasive.

As noted earlier the anticipatory rejection under 102(b) is maintained and consequently the instant rejection is maintained.

12. The rejection of claims 1-5 under 35 U.S.C. 103(a) as being unpatentable over Moinfar et al. (Cancer 98(4): 703-711, August 15, 2003), and further in view of Thompson/ U.S. Patent number 7,029,859 B2 (filed March 5, 2001) is maintained.

Applicant sets forth the criteria for establishing a proper rejection under 103(a) and making a *prima facie* case of obviousness, see Remarks submitted March 3, 2010, pages 13-15 and 17-19. Applicant's arguments are based on the primary reference, Moinfar does not teach the claimed invention. Applicant's arguments and points of view have been carefully considered, but found unpersuasive.

As noted earlier the anticipatory rejection under 102(a) is maintained and consequently the instant rejection is maintained.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached Monday through Saturday, 8 am to 8 pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The

Art Unit: 1643

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
27 March 2010

/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643